

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health)

NOTIFICATION

New Delhi, the 16th March, 2006

G.S.R. 160(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 24th February, 2005, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number G.S.R. 105(E), dated the 24th February, 2005, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 25th February, 2005;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely :—

1. (1) These rules may be called the Drugs and Cosmetics (2nd Amendment) Rules, 2006.
- (2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, for Schedule H, the following Schedule shall be substituted, namely :—

SCHEDULE—H

(See Rules 65 and 97)

PRESCRIPTION DRUGS

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| 1. ABACAVIR | 13. ALLOPURINOL |
| 2. ABCIXIMAB | 14. ALPHACHYMOTRYPSIN |
| 3. ACAMPROSATE CALCIUM | 15. ALPRAZOLAM |
| 4. ACEBUTOL HYDROCHLORIDE | 16. ALPROSTADIL |
| 5. ACLARUBICIN | 17. AMANTADINE HYDROCHLORIDE |
| 6. ALBENDAZOLE | 18. AMIFOSTINE |
| 7. ALCLOMETASONE DIPROPIONATE | 19. AMIKACIN SULPHATE |
| 8. ACTILYSE | 20. AMILORIDE HYDROCHLORIDE |
| 9. ACYCLOVIR | 21. AMINEPTINE |
| 10. ADENOSINE | 22. AMINOGLUTETHIMIDE |
| 11. ADRENOCORTICOTROPHIC HORMONE (ACTH) | 23. AMINOSALICYLIC ACID |
| 12. ALENDRONATE SODIUM | 24. AMIODARONE HYDROCHLORIDE |
| | 25. AMITRIPTYLINE |
| | 26. AMLODIPINE BESYLATE |
| | 27. AMOSCANATE |
| | 28. AMOXOPINE |
| | 29. AMRINONE LACTATE |
| | 30. ANALGIN |
| | 31. ANDROGENIC ANABOLIC, OESTROGENIC & PROGESTATIONAL SUBSTANCES |
| | 32. ANTIBIOTICS |
| | 33. APRACLOMIDINE |
| | 34. APROTININ |
| | 35. ORGANIC COMPOUND OF ARSENIC |
| | 36. ARTEETHER |
| | 37. ARTEMETHER |
| | 38. ARTESUNATE |
| | 39. ARTICAIN HYDROCHLORIDE |
| | 40. ATENOLOL |
| | 41. ATRACURIUM BESYLATE INJECTION |
| | 42. ATORVASTATIN |
| | 43. AURANOFIN |
| | 44. AZATHIOPRINE |
| | 45. AZTREONAM |
| | 46. BACAMPICILLIN |
| | 47. BACLOFEN |
| | 48. BALSALAZIDE |
| | 49. BAMBUTEROL |
| | 50. BARBITURIC ACID |
| | 51. BASILIXIMAB |
| | 52. BENAZEPRIL HYDROCHLORIDE |
| | 53. BENIDIPINE HYDROCHLORIDE |
| | 54. BENSERAZIDE HYDROCHLORIDE |
| | 55. BETAHISTINE DIHYDROCHLORIDE |

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| 56. BETHANIDINE SULPHATE | 99. CEFUROXIME |
| 57. BEZAFIBRATE | 100. CELECOXIB |
| 58. BICALUTAMIDE | 101. CENTCHROMAN |
| 59. BICLOTYMOL | 102. CENTBUTINDOLE |
| 60. BIFONAZOLE | 103. CENTPROPazine |
| 61. BIMATOPROST | 104. CETIRIZINE HYDROCHLORIDE |
| 62. BIPERIDEN HYDROCHLORIDE | 105. CHLORDIAZEPOXIDE |
| 63. BIPHENYL ACETIC ACID | 106. CHLORMEZANONE |
| 64. BITOSCANATE | 107. CHLORPHENIRAMINE MALEATE |
| 65. BLEOMYCIN | 108. CHLORPROMAZINE |
| 66. PRIMONIDINE TARTRATE | 109. CHLORZOXAZONE |
| 67. BROMHEXINE HYDROCHLORIDE | 110. CICLOPIROX OLAMINE |
| 68. BROMOCRIPTINE MESYLATE | 111. CIMETIDINE |
| 69. BUDESONIDE | 112. CINNARIZINE |
| 70. BULAQUINE | 113. CIPROFLOXACIN HYDROCHLORIDE
MONOHYDRATE/LACTATE |
| 71. BUPIVACAINE HYDROCHLORIDE | 114. CISPLATIN |
| 72. BUPROPION | 115. CITALOPRAM HYDROBROMIDE |
| 73. BUSPIRONE | 116. CLARITHROMYCIN |
| 74. BUTENAFINE HYDROCHLORIDE | 117. CLAVULANIC ACID |
| 75. BUTORPHANOL TARTRATE | 118. CLIDINIUM BROMIDE |
| 76. CABERGOLINE | 119. CLINDAMYCIN |
| 77. CALCIUM DOBESILATE | 120. CLOBAZAM |
| 78. CANDESARTAN | 121. CLOBETASOL PROPENATE |
| 79. CAPECITABINE | 122. CLOBETASONE 17-BUTYRATE |
| 80. CAPTOPRIL | 123. CLOFAZIMINE |
| 81. CARBIDOPA | 124. CLOFIBRATE |
| 82. CARBOCISTEINE | 125. CLONAZEPAM |
| 83. CARBOPLATIN | 126. CLONIDINE HYDROCHLORIDE |
| 84. CARBOQUONE | 127. CLOPAMIDE |
| 85. CARISOPRODOL | 128. CLOPIDOGREL BISULPHATE |
| 86. L-CARNITINE | 129. CLOSTEBOL ACETATE |
| 87. CARTEOLOL HYDROCHLORIDE | 130. CLOTRIMAZOLE |
| 88. CARVEDILOL | 131. CLOZAPINE |
| 89. CEFADROXYL | 132. CODEINE |
| 90. CEFATOXIME SODIUM | 133. COLCHICINE |
| 91. CEFAZOLIN SODIUM | 134. CORTICOSTEROIDS |
| 92. CEFDINIR | 135. COTRIMOXAZOLE |
| 93. CEFEPIME HYDROCHLORIDE | 136. CYCLANDELATE |
| 94. CEFETAMET PIVOXIL | 137. CYCLOSPORINS |
| 95. CEFPIROME | 138. DACLIZUMAB |
| 96. CEFPODOXIME POXETIL | 139. DANAZOLE |
| 97. CEFTAZIDIME PENTAHYDRATE | 140. DAPSONE |
| 98. CEFTIZOXIME SODIUM | 141. DESLORATADINE |

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| 142. DESOGESTROL | 184. ETHAMBUTOL HYDROCHLORIDE |
| 143. DEXRAZOXANE | 185. ETHAMSYLATE |
| 144. DEXTRANOMER | 186. ETHINYLOESTRADIOL |
| 145. DEXTROMETHORPHAN HYDROMIDE | 187. ETHIONAMIDE |
| 146. DEXTROPROPOXYPHENE | 188. ETIDRONATE DISODIUM |
| 147. DIAZAPAM | 189. ETODOLAC |
| 148. DIAZOXIDE | 190. ETOMIDATE |
| 149. DICLOFENAC SODIUM/POTASSIUM/ACID | 191. ETOPOSIDE |
| 150. DICYCLOMIN HYDROCHLORIDE | 192. EXEMESTANE |
| 151. DIDANOSINE | 193. FAMCICLOVIR |
| 152. DIGOXINE | 194. FAMOTIDINE |
| 153. DILAZEP HYDROCHLORIDE | 195. FENBENDAZOLE |
| 154. DILTIAZEM | 196. FENOFIBRATE |
| 155. DINOPROSTONE | 197. FEXOFENADINE |
| 156. DIPHENOXYLATE, ITS SALTS | 198. FINASTERIDE |
| 157. DIPIVEFRIN HYDROCHLORIDE | 199. FLAVOXATE HYDROCHLORIDE |
| 158. Di-SODIUM PAMIDRONATE | 200. 5-FLUOROURACIL |
| 159. DISOPYRAMIDE | 201. FLUDARABINE |
| 160. DOCETAXEL | 202. FLUFENAMIC ACIDS |
| 161. DOMPERIDONE | 203. FLUNARIZINE HYDROCHLORIDE |
| 162. DONEPEZIL HYDROCHLORIDE | 204. FLUOXETINE HYDROCHLORIDE |
| 163. DOPAMINE HYDROCHLORIDE | 205. FLUPENTHIXOL |
| 164. DOTHIEPIN HYDROCHLORIDE | 206. FLUPHENAZINE ENANTHATE AND DECANOATE |
| 165. DOXAPRAM HYDROCHLORIDE | 207. FLURAZEPAM |
| 166. DOXAZOSIN MESYLATE | 208. FLURBIPROFEN |
| 167. DOXEPIN HYDROCHLORIDE | 209. FLUTAMIDE |
| 168. DOXORUBICIN HYDROCHLORIDE | 210. FLUTICASONE PROPIONATE |
| 169. DROTRECOGIN-ALPHA | 211. FLUVOXAMINE MALEATE |
| 170. EBASTINE | 212. FORMESTANE |
| 171. ECONOZOLE | 213. FOSFESTRIL SODIUM |
| 172. EFAVIRENZ | 214. FOSINOPRIL SODIUM |
| 173. ENALAPRIL MELEATE | 215. FOSSPHENYTOIN SODIUM |
| 174. ENFENAMIC ACID | 216. FOTEMUSTINE |
| 175. EPINEPHRINE | 217. GABAPENTIN |
| 176. EPIRUBICINE | 218. GALANTHAMINE HYDROBROMIDE |
| 177. EPTIFIBATIDE | 219. GALLAMINE, ITS SALTS, ITS QUATERNARY COMPOUND |
| 178. ERGOT, ALKALOIDS OF WHETHER HYDROGENATED OR NOT, THEIR HOMOLOGUES, SALTS | 220. GANCYCLOVIR |
| 179. ESOMEPRAZOLE | 221. GANIRELIX |
| 180. ESTRADIOL SUCCINATE | 222. GATIFLOXACIN |
| 181. ESTRAMUSTINE PHOSPHATE | 223. GEMCITABINE |
| 182. ETANERCEPT | 224. GEMFIBROZIL |
| 183. ETHACRIDINE LACTATE | 225. GEMTUZUMAB |

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| 226. GENODEOXYCHOLICACID | 268. ITOPRIDE |
| 227. GLICLAZIDE | 269. KETAMINE HYDROCHLORIDE |
| 228. GLIMEPIRIDE | 270. KETOCONAZOLE |
| 229. GLUCAGON | 271. KETOPROFEN |
| 230. GLYCOPYRROLATE | 272. KETOROLAC TROMETHAMINE |
| 231. GLYDIAZINAMIDE | 273. LABETALOL HYDROCHLORIDE |
| 232. GOSERELIN ACETATE | 274. LACIDIPINE |
| 233. GRANISETRON | 275. LAMIVUDINE |
| 234. GUANETHIDINE | 276. LAMOTRIGINE |
| 235. GUGULIPID | 277. LATANOPROST |
| 236. HALOGENATED HYDROXYQUINOLINES | 278. LEFUNOMIDE |
| 237. HALOPERIDOL | 279. LERCANIDIPINE HYDROCHLORIDE |
| 238. HEPARIN | 280. LETROZOLE |
| 239. HEPATITIS B. VACCINE | 281. LEUPROLIDE ACETATE |
| 240. HYALURONIDASE | 282. LEVAMESOLE |
| 241. HYDROCORISONE 17-BUTYRATE | 283. LEVARTERENOL |
| 242. HYDROTALCITE | 284. LEVOBUNOLOL |
| 243. HYDROXIZINE | 285. LEVOCETIRIZINE |
| 244. IBUPROFEN | 286. LEVODOPA |
| 245. IDEBENONE | 287. LEVOFLOXACIN |
| 246. IINDAPAMIDE | 288. LEVOVIST |
| 247. IMIPRAMINE | 289. LIDOFLAZINE |
| 248. INDINAVIR SULPHATE | 290. LINEZPLID |
| 249. INDOMETHACIN | 291. LITHIUM CARBONATE |
| 250. INSULIN HUMAN | 292. LOFEPRAMINE DECANOATE |
| 251. INTERFERON | 293. LOPERAMIDE |
| 252. INTRAVENOUS FATEMULSION | 294. LORAZEPAM |
| 253. IOBITRIDOL | 295. LOSARTAN POTASSIUM |
| 254. IOHEXOL | 296. LOTEPRDNOL |
| 255. IOPAMIDOL | 297. LOVASTATIN |
| 256. IOMEPROL | 298. LOXAPINE |
| 257. IOPROMIDE | 299. MEBENDAZOLE |
| 258. IRBESARTAN | 300. MEBEVERINE HYDROCHLORIDE |
| 259. IRINOTECAN HYDROCHLORIDE | 301. MEDROXY PROGESTERONE ACETATE |
| 260. IRON PREPARATION FOR PARENTERAL USE | 302. MEFENAMIC ACID |
| 261. ISEPAMICINE | 303. MEFLOQUINE HYDROCHLORIDE |
| 262. ISOCARBOXSIDE | 304. MEGESTROL ACETATE |
| 263. ISOFLURANE | 305. MEGLUMINE IOCARMATE |
| 264. ISONICOTNIC ACID HYDRAZINE AND
OTHER-HYDRAGINE DERIVATIVES OF
ISONICOTINIC ACID | 306. MELAGENINA |
| 265. ISOSORBIDE DINITRATE/MONONITRATE | 307. MELITRACEN HYDROCHLORIDE |
| 266. ISOTRETINOIN | 308. MELOXICAM |
| 267. ISOXSUPRINE | 309. MEPHENESIN, ITS ESTERS |
| | 310. MEPHENTERMINE |

311. MEROPENAM	353. NETILMICIN SULPHATE
312. MESTEROLONE	354. NEVIRAPINE
313. METAXALONE	355. NICERGOLINE
314. METHICILLIN SODIUM	356. NICORANDIL
315. METHOCARBAMOL	357. NIFEDIPINE
316. METHOTRAXATE	358. NIMESULIDE
317. METOCLOPRAMIDE	359. NIMUSTINE HYDROCHLORIDE
318. METOPROLOL TARTRATE	360. NITRAZEPAM
319. METRIZAMIDE	361. NITROGLYCERIN
320. METRONIDAZOLE	362. NORETH ISTERONE ENANTHATE
321. MEXILETINE HYDROCHLORIDE	363. NORFLOXACIN
322. MIANSERIN HYDROCHLORIDE	364. OCTYLONIUM BROMIDE
323. MICONAZOLE	365. OFLOXACIN
324. MIDAZOLAM	366. OLANZAPINE
325. MIFEPRISTONE	367. OMEPRAZOLE
326. MILRINONE LACTATE	368. ORNIDAZOLE
327. MILTEFOSINE	369. ORPHENADRINE
328. MINOCYCLINE	370. ORTHOCLONE STERILE
329. MINOXIDIL	371. OXAZEPAM
330. MIRTAZAPINE	372. OXAZOLIDINE
331. MISOPROSTOL	373. OXCARBAZEPINE
332. MITOXANTRONE HYDROCHLORIDE	374. OXETHAZAINE HYDROCHLORIDE
333. MIZOLASTINE	375. OXICONAZOLE
334. MOCLOBEMIDE	376. OXOLINIC ACID
335. MOMETASONE FUROATE	377. OXPRENOLOL HYDROCHLORIDE
336. MONTELUKAST SODIUM	378. OXYBUTYNIN CHLORIDE
337. MORPHAZINAMIDE HYDROCHLORIDE	379. OXYFEDRINE
338. MOSAPRIDE	380. OXYMETAZOLINE
339. MOXIFLOXACIN	381. OXYPHENBUTAZONE
340. MYCOPHENOLATE MOFETIL	382. OXYTOCIN
341. NADIFLOXACIN	383. OZOTHINE
342. NADOLOL	384. PACLITAXEL
343. NAFARELIN ACETATE	385. PANCURONIUM BROMIDE
344. NALIDIXIC ACID	386. PANTOPRAZOLE
345. NAPROXEN	387. PARA-AMINO BENZENE SULPHONAMIDE, ITS SALTS & DERIVATIVES
346. NARCOTIC DRUGS LISTED IN NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES ACT, 1985	388. PARA-AMINO SALICYLIC ACID, ITS SALTS, ITS DERIVATIVES
347. NATAMYCIN	389. PARECOXIB
348. NATEGLINIDE	390. PAROXETINE HYDROCHLORIDE
349. N-BUTYL-2-CYANOACRYLATE	391. D-PENICILLAMINE
350. NEBIVOLOL	392. PENTAZOCINE
351. NEBUMETONE	393. PENTOXIFYLLINE
352. NELFINAVIR MESILATE	394. PEPLEOMYCIN

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| 395. PHENELZINEH SULPHATE | 435. RITONAVIR |
| 396. PHENOBARBITAL | 436. RITODRINE HYDROCHLORIDE |
| 397. PHENOTHIAZINE, DERIVATIVES OF AND
SALTS OF ITS DERIVATIVES | 437. RITUXIMAB |
| 398. PHENYL BUTAZINE | 438. RIVASTIGMINE |
| 399. PIMOZIDE | 439. ROCURONIUM BROMIDE |
| 400. PINDOLOL | 440. ROPINIROLE |
| 401. PIOGLITAZONE HYDROCHLORIDE | 441. ROXACIN |
| 402. PIRACETAM | 442. ROSIGLITAZONE MELEATE |
| 403. PIROXICAM | 443. SALBUTAMOL SULPHATE |
| 404. PITUITARY GLAND, ACTIVE PRINCIPLES OF,
NOT OTHERWISE SPECIFIED IN THIS
SCHEDULE AND THEIR SALTS | 444. SALICYL-AZO-SULPHAPYRIDINE |
| 405. POLIDOCANOL | 445. SALMON CALCITONIN |
| 406. POLYESTRADIOL PHOSPHATE | 446. SAQUINAVIR |
| 407. PORACTANT ALFA | 447. SATRANIDAZOLE |
| 408. PRAZICANTEL | 448. SECNIDAZOLE |
| 409. PREDNIMUSTINE | 449. SEPTOPAL BEADS & CHAINS |
| 410. PREDNISOLONE STEAROYLGLYCOLATE | 450. SERRATIOPEPTIDASE |
| 411. PRENOXDIAZIN HYDROCHLORIDE | 451. SERTRALINE HYDROCHLORIDE |
| 412. PROMAZINE HYDROCHLORIDE | 452. SIBUTRAMINE HYDROCHLORIDE |
| 413. PROMEGESTONE | 453. SILDENAFIL CITRATE |
| 414. PROPAFENON HYDROCHLORIDE | 454. SIMVASTATIN |
| 415. PROPANOLOL HYDROCHLORIDE | 455. SIROLIMUS |
| 416. PROPOFOL | 456. SISOMICIN SULPHATE |
| 417. PROTRISTYLINE HYDROCHLORIDE | 457. S-NEOMINOPHAGEN |
| 418. PYRAZINAMIDE | 458. SODIUM PICOSULPHATE |
| 419. PYRVINIUM | 459. SODIUM CROMOGLYCAT |
| 420. QUETIAPINE FUMERATE | 460. SODIUM HYALURONATE |
| 421. QUINAPRIL | 461. SODIUM VALPROATE |
| 422. QUINIDINE SULPHATE | 462. SODIUM AND MAGLUMINE
IOTHALAMATES |
| 423. RABEPRazole | 463. SOMATOSTATIN |
| 424. RACECADOTRIL | 464. SOMATOTROPIN |
| 425. RALOXIFENE HYDROCHLORIDE | 465. SOTALOL |
| 426. RAMIPRIL HYDROCHLORIDE | 466. SPARFLOXACIN |
| 427. RANITIDINE | 467. SPECTINOMYCIN HYDROCHLORIDE |
| 428. RAUWOLFIA, ALKALOIDS OF, THEIR SALTS,
DERIVATIVES OF THE ALKALOIDS OR
RAUWOLFIA | 468. SPIRONOLACTONE |
| 429. REBOXETINE | 469. STAVUDINE |
| 430. REPAGLINIDE | 470. SUCRALFATE |
| 431. REPROTEROL HYDROCHLORIDE | 471. SULPHADOXINE |
| 432. RILMENIDINE | 472. SULPHAMETHOXINE |
| 433. RILUZONE | 473. SULPHAMETHOXYPYRIDAZINE |
| 434. RISPERIDONE | 474. SULPHAPHENAZOLE |
| | 475. SULPIRIDE |
| | 476. SULPROSTONE HYDROCHLORIDE |
| | 477. SUMATRIPTAN |

478. TACRINEHYDROCHLORIDE
 479. TAMSULOSIN HYDROCHLORIDE
 480. TRAPIDIL
 481. TEGASEROD MALEATE
 482. TEICOPLANIN
 483. TELMISARTAN
 484. TEMOZOLAMIDE
 485. TERAZOSIN
 486. TERBUTALINE SULPHATE
 487. TERFENADINE
 488. TERIZIDONE
 489. TERLIPRESSIN
 490. TESTOSTERONE UNDECOANOATE
 491. TERATOLOL HYDROCHLORIDE
 492. THALIDOMIDE
 493. THIACETAZONE
 494. THICOLCHICOSIDE
 495. THIOPROPAZATE, ITS SALTS
 496. THYMOGENE
 497. THYMOSIN-ALPHA 1
 498. TIAPROFENIC ACID
 499. TIBOLONE
 500. TIMOLOL MALEATE
 501. TINIDAZOLE
 502. TIZANIDINE
 503. TABRAMYCIN
 504. TOLFENAMIC ACID
 505. TOPIRAMATE
 506. TOPOTECAN HYDROCHLORIDE
 507. TRAMADOL HYDROCHLORIDE
 508. TRANEXAMIC ACID
 509. TRANYLCYPROMINE, ITS SALTS
 510. TRAZODONE
 511. TRETINOIN
 512. TRIFLUPERAZINE
 513. TRIFLUPERIDOL HYDROCHLORIDE
 514. TRIFLUSAL

515. TRIMETAZIDINE DIHYDROCHLORIDE
 516. TRIMIPRAMINE
 517. TRIPOTASSIUM DICITRATE BISMUTHATE
 518. TROMANTADINE HYDROCHLORIDE
 519. UROKINASE
 520. VALSARTAN
 521. VASOPRESSIN
 522. VECURONIUM BROMIDE
 523. VENLAFAXINE HYDROCHLORIDE
 524. VERAPAMIL HYDROCHLORIDE
 525. VERTEPORFIN
 526. VINCRISTINE SULPHATE
 527. VINBLASTINE SULPHATE
 528. VINDESINE SULPHATE
 529. VINORELBINE TATRATE
 530. XIPAMIDE
 531. ZIDOVUDINE HYDROCHLORIDE
 532. ZIPRASIDONE HYDROCHLORIDE
 533. ZOLEDRONIC ACID
 534. ZOLPIDEM
 535. ZOPICLONE
 536. ZUCLOPENTHIXOL

- Note** 1. Preparations exempted under proviso to para 2 of Note to Schedule X shall also be covered by this Schedule.
2. The salts, esters, derivatives and preparations containing the above substances excluding those intended for topical or external use (except ophthalmic and ear/nose preparations containing antibiotics and/or steroids) are also covered by this Schedule.
3. The inclusion of a substance in this Schedule does not imply or convey that the substance is exempted from the provisions of Rule 122A/122B".

[No. X-11014/3/2004-DMS & PFA]

RITA TEOTIA, Jt. Secy.

Foot Note :— The Principal Rules were published in the Official Gazette *vide* notification No. F. 28-10/45-H (1) dated 21-12-1945 and last amended *vide* No. GSR 26(E) dated 19-1-2006.